

Summary of provisions in DEA's proposed rule for disposal of controlled substances from long-term care facilities under the Secure and Responsible Drug Disposal Act of 2010.

The DEA proposes the following options for collection of controlled substances from ultimate users (patients) and from individuals authorized to dispose of a decedent's property:

- **Collection receptacle locations (i.e., permanent drop-off boxes)** – operated by authorized retail pharmacies, manufacturers, distributors, and reverse distributors, in addition to law enforcement agencies.
- **Mail-back programs** – operated by authorized manufacturers, distributors, reverse distributors, retail pharmacies, and law enforcement agencies.
- **Take-back events** – conducted by law enforcement agencies only.

For all collection methods, controlled and noncontrolled substances may be comingled in the collection receptacle.

For long-term care facilities (LTCF), DEA proposes to authorize staff to dispose of controlled substances on behalf of residents only if there is a collection receptacle operated in the LTCF by an authorized retail pharmacy.

DEA defines a LTCF as “a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.” 21 CFR 1300.01(b).

DEA's explanatory text describes a distinction between LTCF's and hospitals in how medicines are dispensed and provided to patients.

“Generally, controlled substances are prescribed by a LTCF resident's physician and dispensed by the resident's pharmacist; such controlled substances are owned by the resident. This is in contrast with patients in a hospital where controlled substances are dispensed dose by dose and remain under the possession and control of the registered dispenser, the hospital. Accordingly, a LTCF may secure its residents' controlled substances for custodial purposes only. The controlled substances remain in the lawful possession of the resident, the ultimate user. As with any other ultimate user, prior to the enactment of the Disposal Act, a LTCF resident in lawful possession of dispensed controlled substances could not distribute those substances to another person, even for the purpose of disposal. “

The DEA's proposed rule also states clearly that residents of LTCFs may utilize the other collection methods authorized under the proposed rule:

“Although LTCFs may only dispose of their residents' controlled substances through collection receptacles at the LTCF, LTCF residents themselves may utilize any other disposal method available to ultimate users, including mail-back programs and take-back events. Care should be taken to ensure that LTCF residents' use of mail-back programs and take-back events does not result in the accumulation of controlled substances in a single location susceptible to internal or external diversion threats, as discussed above.”